Miller, Diane M. (CDC/NIOSH/EID)

From: Dolores.Ambs@sensient.com
Sent: Friday, November 18, 2011 6:11 PM
To: NIOSH Docket Office (CDC)
Cc: Jim.McCarthy@sensient.com; Ed.Savard@sensient.com
Subject: NIOSH Document "Criteria for Recommended Standard: Occupational Exposure to Diacetyl and 2,3 - Pentanedione"
Attachments: MX-5500N_20111118_185912.pdf

Please find attached Sensient Flavors LLC response to: NIOSH Document "Criteria for Recommended Standard: Occupational Exposure to Diacetyl and
2,3 - Pentanedione".

(See attached file: MX-5500N_20111118_185912.pdf)

Best regards,

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18 November 2011

RE: Comments on the NIOSH Document "Criteria for a Recommended Standard: Occupational Exposure to Diacetyl and 2,3-Pentanedione."
76 *Fed. Reg.* 44338. 25 July 2011.
Docket Number NIOSH -245.

Dear Sir/Ms.:

Sensient Flavors LLC (Sensient Flavors) is pleased to respond to the request for comments on the document "Criteria for a Recommended Standard: Occupational Exposure to Diacetyl and 2,3-Pentanedione" ("Criteria Document") published by the National Institute of Occupational Safety and Health (NIOSH). 76 *Fed. Reg.* 44338. 25 July 2011.

In addition to the comments contained herein, as one of the larger members of The Flavor and Extract Manufacturers Association of the United States (FEMA), Sensient Flavors also adopts FEMA's comments to the Criteria Document. [1]

About Sensient Flavors LLC

Sensient Flavors is a part of Sensient Technologies Corporation, a global, publicly traded company with operations in more than 30 countries including the United States. Sensient Flavors' headquarters is in Indianapolis, Indiana.

[1] It should be noted, however, that FEMA's discussion of the unusually high levels of diacetyl in the manufacture of compounded butter flavors in microwave popcorn production and in other flavor types is not applicable to Sensient Flavors. Indeed, Sensient Flavors has never manufactured butter flavors for microwave popcorn with diacetyl levels anywhere near 10.0% or at levels well above 1.0%.

Sensient Flavors offers flavor solutions to help our clients bring life to their products. The company's approach to advanced product development capabilities are reknown in the industry. With an extensive portfolio of proprietary technologies, Sensient Flavors creates custom flavor solutions and products. Continuous development of our product range and ongoing investment in state of the art technology and production facilities allows Sensient Flavors to create innovative products, tap new markets and meet the innovation needs of our customers.

Since its inception, Sensient Flavors has had an unwavering commitment to the health and safety our workforce. Indeed, our Indianapolis facility has an excellent record of compliance with all applicable state and federal regulations relative to workplace safety. Sensient Flavors has actively supported and participated in FEMA's efforts in the area of respiratory health and safety since it began offering programs in 1997.

General Comments on the NIOSH Criteria Document

The 1985 Indiana Bakers Study

The Criteria Document makes multiple references to the 1985 NIOSH evaluation of a baking facility in Indiana that used flavorings with diacetyl, and where "two workers with fixed obstructive lung disease *suggestive* of bronchiolitis obliterans were observed." (emphasis added) This document did not identify diacetyl or any other chemical as a causative agent. Indeed, a fair reading of this document indicates that NIOSH was unable to reach any conclusions whatsoever as to the cause of the respiratory condition of these two workers.

In Sensient Flavor's view, to suggest that the 1985 baking facility study is somehow germane to the establishment of a recommended standard for diacetyl and 2,3-Pentanedione is a stretch, at best. Moreover, if NIOSH intends to use this study in the Criteria Document, it should explain why there are no case reports of respiratory disease in the flavor manufacturing workplace for at least 10 years following the study, despite the fact that the use and production of flavors containing diacetyl and 2,3-Pentanedione continued without interruption in multiple companies and in multiple contexts across the country.

For these reasons, Sensient Flavors believes all references to the 1985 Indiana baking facility study should be removed from the Criteria Document.

The Recommended Exposure Limit (REL) for 2,3-Pentanedione

Sensient Flavors echoes the comments of FEMA on this subject. There is simply no empirical scientific evidence cited in the Criteria Document that indicates 2,3-Pentanedione exposure causes bronchiolitis obliterans, or any other respiratory disease. Sensient Flavors believes that all references to 2,3-Pentanedione and all standards being recommended for exposure to that chemical, should be removed from the Criteria Document.

The Criteria Document's "Action Levels" and "Short Term Exposure Levels"

FEMA has discussed and offered a critique of the proposed RELs for both diacetyl and 2,3-Pentanedione. In Sensient Flavor's view, that same discussion and analysis apply to the action levels and short term exposure levels for these chemicals that have been proposed by NIOSH. To the extent FEMA's critique causes NIOSH to re-evaluate and adjust these RELs, the action levels and short term exposure levels should be similarly modified.

Restrictive versus Obstructive Lung Abnormalities

The proposition advanced in the Criteria Document that restrictive, rather than obstructive, lung function abnormality is related to diacetyl exposure is speculative and not proven. The Criteria Document references just three alleged instances, on Pages 69, 76 and 77, of restrictive lung functions. The first reference is to a Wisconsin flavor manufacturer, where diacetyl in starter distillate is just one component of many, including bacteria, in use in the manufacturing process. Two of fifteen employees *potentially* exposed to flavoring-related chemicals were evaluated by NIOSH as having restrictive abnormalities. There is no evidence presented that diacetyl, or any other flavoring chemical, is the causative agent.

The second reference is to an Indiana flavoring manufacturer, where NIOSH claims diacetyl is used nearly daily but acknowledges that chemical exposures are diverse. Areas within this plant that are incorrectly identified as having higher potential for diacetyl exposure include extract/distillation and dry blend. In fact, this manufacturer monitored the dry blend area and found diacetyl levels below 2 ppb; there is no use of diacetyl in the extract/distillation area, so there are no data for this location. It appears that NIOSH chose to include these areas in the analysis to bolster the hypothesis that diacetyl is a causative agent in the development of restrictive lung function. But the opposite appears to be true: if employees working in these two areas have restrictive lung function, it could not have been caused by diacetyl because the chemical was not present. Significantly, the Health Hazard Evaluation (HHE) that was generated as a result of NIOSH's evaluation of this facility conceded that it could not be concluded that diacetyl was the cause of the purported respiratory issues experienced by these workers.

The third instance of alleged restrictive lung function in employees references a bakery mix plant where diacetyl could not be detected through air testing. Instead, 2,3-Pentanedione was detected. NIOSH makes no attempt to correlate employee exposure to work station or the handling of 2,3-Pentanedione.

Based upon the problems and limitations associated with the science in this area, Sensient Flavors believes that all references to diacetyl and 2,3-Pentanedione causing and/or being associated with restrictive lung function abnormalities should be removed from the Criteria Document.

Possible Synergistic Effects

The Criteria Document acknowledges possible synergistic effects from flavoring chemicals other than diacetyl or 2,3-Pentanedione that may contribute to lung abnormalities. When this question was raised at the public hearing, NIOSH replied that, since such flavoring chemicals were often used simultaneously, diacetyl would serve as a surrogate with an exposure level to represent all associated compounds. But this approach *avoids* establishing a causal effect between diacetyl, other chemicals simultaneously in use, and lung abnormalities. Worse, if it were scientifically proven that another flavoring compound has more deleterious effects, the more dangerous chemical could be used in higher amounts to replace diacetyl, thus resulting in greater risk to employees.

On page 10, line 5 the Criteria Document indicates that the standard sought to be set is "necessary to . . . prevent flavorings-related lung disease." Since synergistic effects have not been evaluated, it is impossible for a single REL to accomplish this stated goal. Further, even if diacetyl is harmful, limiting the use of diacetyl may or may not result in disease prevention.

Data Quality Concerns/Inconsistencies

The Criteria Document indicates that spirometry data from the Indiana flavoring manufacturer was analyzed using software (SPIROLA) to adjust for data quality. This is the only reference to data quality in the draft report. It is curious – and inconsistent - that SPIROLA was not utilized to evaluate and adjust respiratory function data from the other studies and reviews conducted by NIOSH. What is NIOSH's rationale for using this software to evaluate only the Indiana data?

Economic Impact

Sensient Flavors has already established excellent engineering controls to minimize employee exposure to diacetyl and 2,3-Pentanedione. Nevertheless, the additional economic cost to the company and, presumably, to other flavor manufacturers to attain the proposed REL will be significant. It is estimated that the cost of additional engineering controls for Sensient Flavors' single manufacturing location in Indianapolis will be in the range of $4 - $6 million. These costs would be incurred without a clearly defined benefit for the incremental reduction in potential employee exposures. There will also be additional, ongoing operating costs associated with the design changes, as employee productivity decreases and scheduling conflicts arise.

Specific Comments on the NIOSH Criteria Document

Page v: "While the focus of this document is on diacetyl and 2,3-Pentanedione, NIOSH has concern about other flavoring substitutes with structural similarities to diacetyl or moieties that are biologically active and capable of producing similar toxic effects as diacetyl. Therefore, NIOSH recommends that such exposures also be considered and controlled to as low as reasonably achievable."

This statement is not supported by any facts. If there is evidence of harmful effects, then the exact compounds should be identified. If not, this statement should be removed. Terms such as "similar toxic effects" and "as low as reasonably achievable" are inappropriately vague and imply hazards without any factual basis. Sensient Flavors has similar concerns with Section 1.1 Purpose, where it states that "the intended outcome of the [criteria] document is to ... prevent flavorings-related lung diseases."

Page 19: "When the encapsulated powder comes into contact with water, or saliva, a 'flavor burst' occurs where the release of the flavor from the encapsulation is generally fast and complete upon contact with the moisture."

This is a gross overstatement and oversimplification of the functionality of encapsulated powder flavorings. While this may be true of ***some*** flavoring encapsulated technologies, it is not true of all of them. And it is certainly not true that contact with common saliva will always trigger a "flavor burst" and "release" of the flavor. Indeed, most encapsulated flavorings that Sensient Flavors manufacturers will not release unless heated and exposed to moisture at levels well beyond the temperature of saliva or even hot water. Sensient Flavors believes this statement should be significantly modified to reflect the highly variable nature of the different encapsulated powder flavoring products made by companies in the flavoring industry.

Page 21: "For example, respiratory issues have been anecdotally reported for cheese production (Wisconsin), yogurt production (Ohio), and potato chip manufacturing."

Sensient Flavors does not believe that a scientifically based document like the Criteria Document should contain anecdotal report information without more. Especially when, as here, the anecdotal reports do not attribute the purported respiratory issues to exposure to flavoring chemicals or, more specifically, diacetyl and 2,3-Pentanedione.

Page 236: "For some processes, employers may need to provide workers with showers and require them to shower before leaving work."

In Sensient Flavors' view, this comment either needs to be fully developed or deleted. No benefit is derived from NIOSH suggesting a possible showering requirement for "some processes," but never identifying what processes, specifically, might make showering necessary. The Criteria Document provides the reader with no practical guidance. Given the potential implications a showering requirement could have on employers under the Fair Labor Standards Act, the OSHA Act and other federal and state statutes, if NIOSH is not prepared to specifically identify the "processes" in issue, this language should be deleted.

Page 274: "Smoking diacetyl-exposed workers appear to have lower excess risk of obstruction than never-smoking flavoring exposed workers."

This needs to be explained. The notion that smoking could somehow have a protective effect for flavoring exposed workers seems, on its face, to make no scientific sense.

Sensient Flavors requests that NIOSH explain how it believes this phenomenon can occur if in fact there is a dose-response relationship between diacetyl exposure and abnormal lung function.

Page 275: "If a worker with asthma symptoms does not have changes over time on medical monitoring spirometry, a methacholine challenge test may be necessary to determine if the worker has airways hyper responsiveness as occurs in asthma."

If Sensient Flavors understands this statement correctly, NIOSH is proposing that a methacholine challenge test be administered to a worker with stable medical monitoring spirometry results. If that understanding is correct, what is the scientific justification for this?

Page 294: "What proportions of excess obstructive lung disease in food production workers and in cooks are attributable to flavorings exposure?"

Sensient Flavors understands that some study has already been performed in this area involving workers employed by ARAMARK. If the results of that study are discussed somewhere in the Criteria Document, please identify where that is. If it is not in the Criteria Document, NIOSH should explain why it is not.

Sensient would be pleased to respond to any questions and comments, and requests for additional information that you may have. My email address is jim.mccarthy@sensient.com.

Sincerely,

James P. McCarthy
President, Flavors & Fragrances, LLC